

SEP 14 2004

**510(k) Summary - Precinorm ® Universal Plus and Precipath
® Universal Plus Control Sera**

Introduction	According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence
<hr/>	
Device Name	Proprietary name: Roche Diagnostics Precinorm ® Universal Plus and Precipath ® Universal Plus Control Sera (Precinorm® U Plus and Precipath ® U Plus) Common name : Control Sera Classification name: Multi-analyte controls, all kinds (assayed and unassayed)
<hr/>	
Device description	Precinorm ® U Plus/ Precipath ®U Plus is a quality control product consisting of lyophilized human sera with constituents added as required to obtain desired component levels. Concentrations of control components have been adjusted to represent normal and pathological ranges.
<hr/>	
Intended use	Precinorm ® U Plus/ Precipath ® U Plus are for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet

Continued on next page

510(k) Summary - Precinorm® Universal and Precipath® Universal Control Sera ,Continued

Substantial Equivalence Roche claims substantial equivalence to the currently marketed Roche Diagnostics Precinorm® U Plus/ Precipath® U Plus (K993360).

Submitter name, address, contact Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250
(317) 521-3723

Contact person: Theresa M. Ambrose

Date prepared: August 18, 2004

Substantial Equivalence – Device comparison The table below compares Precinorm® U Plus/ Precipath® U Plus with the predicate device (currently marketed Precinorm® U Plus/ Precipath® U Plus).

Characteristic	Precinorm® U Plus/ Precipath® U Plus (Predicate device, K993360)	Precinorm® U Plus/ Precipath® U Plus (Modified Device)
Intended Use	For use in the quality control of Roche methods for the quantitative determination of substrates, electrolytes, lipids, enzymes, proteins, and selected drugs. The control is used for monitoring accuracy or precision both for manual techniques and assays on automated clinical chemistry analyzers.	For use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet
Format	Lyophilized control serum based on human serum. Concentrations of control components have been adjusted to represent normal and pathological ranges.	Same

Continued on next page

510(k) Summary - Precinorm® Universal and Precipath® Universal Control Sera ,Continued

Substantial Equivalence – Device comparison (continued)

Characteristic	Precinorm® U Plus/ Precipath® U Plus (Predicate device, K993360)	Precinorm® U Plus/ Precipath® U Plus (Modified Device)
Stability	<p><u>Unopened</u> Until expiration date at 2-8°C</p> <p><u>Opened/reconstituted:</u> 12 hours at 25 °C 5 days at 4°C 1 month at -20 °C when frozen once</p> <p><u>Bicarbonate in reconstituted serum</u> 2 days in closed bottle 1 hour in open bottle <u>Bilirubin in reconstituted serum (protected from light)</u> 2 hours at 25 °C 1 day at 4°C 2 weeks at -20 °C when frozen once</p> <p><u>Inorganic phosphorus in reconstituted serum (protected from light)</u> 5 hours at 25 °C 1 day at 4°C 1 month at -20 °C when frozen once</p>	<p><u>Unopened</u> Same</p> <p><u>Opened/reconstituted:</u> 12 hours at 15-25°C 5 days at 2 to 8°C 4 weeks at -15 to -25 °C when frozen once</p> <p><u>Bicarbonate in reconstituted serum</u> Same <u>Total bilirubin in reconstituted serum (protected from light)</u> 8 hours at 15-25°C 24 hours at 2 to 8°C 2 weeks at -15 to -25 °C when frozen once</p> <p><u>Direct bilirubin in reconstituted serum (protected from light)</u> 4 hours at 15-25°C 8 hours at 2 to 8°C 2 weeks at -15 to -25 °C when frozen once</p>

Continued on next page

510(k) Summary - Precinorm® Universal and Precipath® Universal Control Sera, Continued

Substantial Equivalence – Device comparison (continued)

Characteristic	Precinorm® U Plus/ Precipath® U Plus (Predicate device, K993360)	Precinorm® U Plus/ Precipath® U Plus (Modified Device)
Constituent Analytes from biological additives	<ul style="list-style-type: none"> • ALT (GPT) • AST (GOT) • Albumin • Aldolase • Alkaline Phosphatase • Amylase, total • Amylase, pancreatic • Cholesterol • Cholinesterase • Creatine kinase • γ-GT • GLDH • LD (LDH) • Lipase • Acid phosphatase • Total Protein 	Same
Origin of selected biological additives	<ul style="list-style-type: none"> • Lipase from porcine pancreas • Albumin and total protein from human serum 	<ul style="list-style-type: none"> • Lipase from human pancreas (recombinant) • <u>For Precinorm® U Plus:</u> albumin and total protein from bovine serum • <u>For Precipath® U Plus:</u> same



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 14 2004

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Theresa M. Ambrose, Ph.D. RAC
Regulatory Affairs Principal
Roche Diagnostics
9115 Hague Road
PO Box 50457
Indianapolis, IN 46250-0457

Re: k042389
Trade/Device Name: Precinorm® Universal Plus
Precipath ® Universal Plus Control Sera
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: September 1, 2004
Received: September 2, 2004

Dear Dr. Ambrose:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

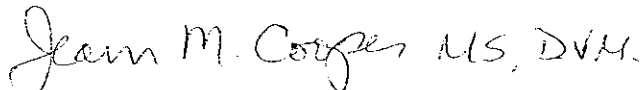
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Jean M. Cooper, MS, D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Precinorm ® Universal Plus and Precipath ® Universal Plus Control Sera

Indications For Use:

Precinorm ® U Plus is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet.
Precipath ® U Plus is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet.

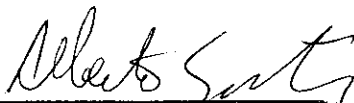
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Division Sign-Off

Page 1 of 1

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K042389